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PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

MARIE A. TEAL,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE, LLC,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-1008-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE, LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 (improperly captioned in Plaintiff's Complaint as "G.D. Searle, LLC") ("Searle") (collectively
4 "Defendants"), and file this Answer to Plaintiff's Complaint ("Complaint"), and would
5 respectfully show the Court as follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
9 Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
10 Defendants may seek leave to amend this Answer when discovery reveals the specific time
11 periods in which Plaintiff was prescribed and used Bextra®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
16 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
18 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of
20 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
21 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
22 providers who are by law authorized to prescribe drugs in accordance with their approval by the
23 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
28 and deny the remaining allegations in this paragraph of the Complaint.

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2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States, including the States of California and New Mexico, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Bextra® in the United States, including the States of California and New Mexico, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

6. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiff claims that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship, and, therefore, deny the same. However, Defendants admit that Plaintiff claims that the parties are diverse. Defendants deny the remaining allegations in this paragraph of the Complaint.

8. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny committing a tort in the States of California and New Mexico, and deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States, including the States of California and New Mexico, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants admit that they do business in the State of Texas. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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Response to Allegations Regarding Interdistrict Assignment

10. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants admit that Bextra® was expected to reach consumers without substantial change from the time of sale. Defendants are without knowledge or information sufficient to

1 form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and,
2 therefore, deny the same. Defendants deny the remaining allegations this paragraph of the
3 Complaint.

4 15. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants are without knowledge or information sufficient to form a belief as to the truth of
9 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants deny remaining the allegations in this paragraph of the Complaint.

11 Answering the unnumbered paragraph following Paragraph 15 of the Complaint,
12 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
13 and deny the remaining allegations in this paragraph of the Complaint.

14 16. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
15 steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that Bextra® was and is safe
16 and effective when used in accordance with its FDA-approved prescribing information.
17 Defendants state that the potential effects of Bextra® were and are adequately described in its
18 FDA-approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny the remaining allegations in this
20 paragraph of the Complaint.

21 17. The allegations in this paragraph of the Complaint are not directed toward Defendants
22 and, therefore, no response is required. To the extent a response is deemed required,
23 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
24 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
25 form a belief as to the truth of such allegations and, therefore, deny the same.

26 18. The allegations in this paragraph of the Complaint are not directed toward Defendants
27 and, therefore, no response is required. To the extent a response is deemed required,
28 Defendants state that Plaintiff fails to provide the proper context for the allegations in this

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1 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
2 form a belief as to the truth of such allegations and, therefore, deny the same.

3 19. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
4 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth
5 of such allegations and, therefore, deny the same.

6 20. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
7 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
8 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful
9 conduct and deny the remaining allegations in this paragraph of the Complaint.

10 21. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,
11 Defendants admit that Celebrex® was launched in the United States in February 1999.
12 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
13 FDA-approved prescribing information. Defendants admit that, during certain periods of time,
14 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
15 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
16 with their approval by the FDA. Defendants admit that, during certain periods of time,
17 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
18 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
19 providers who are by law authorized to prescribe drugs in accordance with their approval by the
20 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
21 directed toward Defendants and, therefore, no response is required. To the extent a response is
22 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
23 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants
24 therefore lack sufficient information or knowledge to form a belief as to the truth of such
25 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this
26 paragraph of the Complaint.

27 22. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
28 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the

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1 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
2 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.
3 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
4 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
5 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
6 this paragraph of the Complaint.

7 23. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
8 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
9 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
10 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
11 allegations in this paragraph of the Complaint.

12 24. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
13 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
14 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
15 the remaining allegations in this paragraph of the Complaint.

16 25. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
17 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
18 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
19 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
20 prescribing information. Defendants state that the potential effects of Bextra® were and are
21 adequately described in its FDA-approved prescribing information, which at all times was
22 adequate and comported with applicable standards of care and law. Defendants deny the
23 remaining allegations in this paragraph of the Complaint.

24 26. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which at all times was adequate and comported with applicable standards of care and law.
28 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-

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1 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
2 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
3 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
4 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
5 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
6 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding
7 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
8 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 27. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
15 this paragraph of the Complaint.

16 28. The allegations in this paragraph of the Complaint are not directed towards Defendants
17 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
18 state that the referenced article speaks for itself and respectfully refer the Court to the article for
19 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
20 the remaining allegations in this paragraph of the Complaint.

21 29. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
22 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November
23 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this
24 paragraph of the Complaint.

25 30. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which at all times was adequate and comported with applicable standards of care and law.

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1 Defendants deny the allegations in this paragraph of the Complaint.

2 31. Defendants state that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants deny the allegations in this
4 paragraph of the Complaint.

5 32. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and
6 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to
7 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this
8 paragraph of the Complaint.

9 33. Defendants state that the referenced article speaks for itself and respectfully refer the
10 Court to the article for its actual language and text. Any attempt to characterize the article is
11 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 34. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug
13 approval meta-analysis study” in this paragraph of the Complaint. Defendants are without
14 sufficient information to confirm or deny such allegations and, therefore, deny the same.
15 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
16 the study for its actual language and text. Any attempt to characterize the study is denied.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 35. The allegations in this paragraph of the Complaint are not directed towards Defendants
19 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
20 state that the referenced article speaks for itself and respectfully refer the Court to the article for
21 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
22 the remaining allegations in this paragraph of the Complaint.

23 36. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
25 deny the remaining allegations in this paragraph of the Complaint.

26 37. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
27 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
28 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 38. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
3 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
4 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 39. Defendants state that the referenced article speaks for itself and respectfully refer the
7 Court to the article for its actual language and text. Any attempt to characterize the article is
8 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 40. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
11 this paragraph of the Complaint.

12 41. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 42. Defendants state that the referenced article speaks for itself and respectfully refer the
16 Court to the article for its actual language and text. Any attempt to characterize the article is
17 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

18 43. Defendants state that the referenced articles speak for themselves and respectfully refer
19 the Court to the articles for their actual language and text. Any attempt to characterize the
20 articles is denied. Defendants deny the remaining allegations in this paragraph of the
21 Complaint.

22 44. Defendants state that the referenced article speaks for itself and respectfully refer the
23 Court to the article for its actual language and text. Any attempt to characterize the article is
24 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 45. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants deny the allegations in this
27 paragraph of the Complaint.

28 46. Defendants state that the referenced article speaks for itself and respectfully refer the

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1 Court to the article for its actual language and text. Any attempt to characterize the article is
2 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
3 paragraph of the Complaint.

4 47. The allegations in this paragraph of the Complaint are not directed towards Defendants
5 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
6 state that the referenced article speaks for itself and respectfully refer the Court to the article for
7 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
8 the remaining allegations in this paragraph of the Complaint.

9 48. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny the allegations in this paragraph of the Complaint.

14 49. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
19 allegations in this paragraph of the Complaint.

20 50. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
27 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
28 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

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1 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
2 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
3 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
4 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Bextra® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants are without knowledge or information
9 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used
10 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
11 allegations in this paragraph of the Complaint.

12 52. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed
13 toward Defendants and, therefore, no response is required. To the extent a response is deemed
14 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
15 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient
16 information or knowledge to form a belief as to the truth of such allegations and, therefore,
17 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in
18 this paragraph of the Complaint.

19 53. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
22 paragraph of the Complaint.

23 54. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
24 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
25 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
26 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
27 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
28 be prescribed by healthcare providers who are by law authorized to prescribe drugs in

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1 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 55. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and
12 deny the remaining allegations in this paragraph of the Complaint.

13 56. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
14 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state
15 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its
16 actual language and text. Any attempt to characterize the letter is denied. Defendants admit
17 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the
18 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual
19 language and text. Any attempt to characterize the letter is denied. Defendants state that the
20 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and
21 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to
22 characterize the transcripts is denied. Defendants state that the referenced study speaks for
23 itself and respectfully refer the Court to the article for its actual language and text. Any attempt
24 to characterize the article is denied. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 57. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
27 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
28 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state

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1 that the referenced press release speaks for itself and respectfully refer the Court to the press
2 release for its actual language and text. Any attempt to characterize the press release is denied.
3 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
4 the article for its actual language and text. Any attempt to characterize the article is denied.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 58. Defendants state that the referenced press release speaks for itself and respectfully refer
8 the Court to the press release for its actual language and text. Any attempt to characterize the
9 press release is denied. Defendants deny any wrongful conduct and deny the remaining
10 allegations in this paragraph of the Complaint.

11 59. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
12 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
13 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
16 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Bextra® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants admit, as indicated in the package insert
22 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
23 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
24 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 60. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which at all times was adequate and comported with applicable standards of care and law.

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1 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
2 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
3 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
4 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

5 61. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
6 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
7 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
8 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
9 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
10 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
11 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Bextra® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 62. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which at all times was adequate and comported with applicable standards of care and law.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 63. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 64. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 65. Defendants deny the allegations in this paragraph of the Complaint.

7 66. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
12 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Bextra® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 67. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the
21 same. Defendants state that the referenced press releases speak for themselves and respectfully
22 refer the Court to the press releases for their actual language and text. Any attempt to
23 characterize the press releases is denied. Defendants state that Bextra® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Bextra® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

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68. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law

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1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
2 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
3 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
4 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
5 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 73. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
12 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
14 paragraph of the Complaint.

15 **Response to First Cause of Action: Negligence**

16 74. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
17 Complaint as if fully set forth herein.

18 75. Defendants state that this paragraph of the Complaint contains legal contentions to
19 which no response is deemed required. To the extent a response is deemed required,
20 Defendants admit that they had duties as are imposed by law but deny having breached such
21 duties. Defendants state that the potential effects of Bextra® were and are adequately described
22 in its FDA-approved prescribing information, which was at all times adequate and comported
23 with applicable standards of care and law. Defendants state that Bextra® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 deny the remaining allegations in this paragraph of the Complaint.

26 76. Defendants state that this paragraph of the Complaint contains legal contentions to
27 which no response is deemed required. To the extent a response is deemed required,
28 Defendants admit that they had duties as are imposed by law but deny having breached such

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1 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
3 this paragraph of the Complaint.

4 77. Defendants state that this paragraph of the Complaint contains legal contentions to
5 which no response is required. To the extent that a response is deemed required, Defendants
6 admit that they had duties as are imposed by law but deny having breached such duties.
7 Defendants state that Bextra® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
9 were and are adequately described in its FDA-approved prescribing information, which was at
10 all times adequate and comported with applicable standards of care and law. Defendants deny
11 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
12 including all subparts.

13 78. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants are without knowledge or information sufficient to form a belief as to the truth of
18 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint.

21 79. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 80. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny

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1 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
2 paragraph of the Complaint.

3 81. Defendants state that Bextra® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Bextra® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 82. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed
10 toward Defendants and, therefore, no response is required. To the extent a response is deemed
11 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
12 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient
13 information or knowledge to form a belief as to the truth of such allegations and, therefore,
14 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in
15 this paragraph of the Complaint.

16 83. Defendants state that the referenced article speaks for itself and respectfully refer the
17 Court to the article for its actual language and text. Any attempt to characterize the article is
18 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
19 paragraph of the Complaint.

20 84. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 85. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
23 damage and deny the remaining allegations in this paragraph of the Complaint.

24 Answering the unnumbered paragraph following Paragraph 85 of the Complaint,
25 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
26 and deny the remaining allegations in this paragraph of the Complaint.

27 **Response to Second Cause of Action: Strict Liability**

28 86. Defendants incorporate by reference their responses to each paragraph of Plaintiff's

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1 Complaint as if fully set forth herein.

2 87. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
4 Defendants admit that Bextra® was expected to reach consumers without substantial change in
5 the condition from the time of sale. Defendants state that Bextra® was and is safe and effective
6 when used in accordance with its FDA-approved prescribing information. Defendants state that
7 the potential effects of Bextra® were and are adequately described in its FDA-approved
8 prescribing information, which was at all times adequate and comported with applicable
9 standards of care and law. Defendants deny that Bextra® is defective or unreasonably
10 dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all
11 subparts.

12 88. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny the allegations in this paragraph of the Complaint.

17 89. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
22 allegations in this paragraph of the Complaint.

23 90. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
28 allegations in this paragraph of the Complaint.

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1 91. Defendants state that this paragraph of the Complaint contains legal contentions to
2 which no response is required. To the extent that a response is deemed required, Defendants
3 are without knowledge or information sufficient to form a belief as to the truth of the
4 allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants
5 state that Bextra® was and is safe and effective when used in accordance with its FDA-
6 approved prescribing information. Defendants state that the potential effects of Bextra® were
7 and are adequately described in its FDA-approved prescribing information, which was at all
8 times adequate and comported with applicable standards of care and law. Defendants deny that
9 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
10 paragraph of the Complaint, including all subparts.

11 92. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
13 Defendants state that Bextra® was and is safe and effective when used in accordance with its
14 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
15 were and are adequately described in its FDA-approved prescribing information, which was at
16 all times adequate and comported with applicable standards of care and law. Defendants deny
17 that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
18 paragraph of the Complaint.

19 93. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
21 Defendants state that Bextra® was and is safe and effective when used in accordance with its
22 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
23 were and are adequately described in its FDA-approved prescribing information, which was at
24 all times adequate and comported with applicable standards of care and law. Defendants deny
25 that Bextra® is defective and deny the remaining allegations in this paragraph of the Complaint.

26 94. Defendants state that this paragraph of the Complaint contains legal contentions to
27 which no response is deemed required. To the extent a response is deemed required,
28 Defendants deny the allegations in this paragraph of the Complaint.

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1 95. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
6 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
7 Complaint.

8 96. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
13 allegations in this paragraph of the Complaint.

14 97. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
16 Defendants state that Bextra® was and is safe and effective when used in accordance with its
17 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
18 were and are adequately described in its FDA-approved prescribing information, which was at
19 all times adequate and comported with applicable standards of care and law. Defendants admit
20 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®
21 in the United States to be prescribed by healthcare providers who are by law authorized to
22 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
23 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
24 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
25 healthcare providers who are by law authorized to prescribe drugs in accordance with their
26 approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is defective,
27 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
28 paragraph of the Complaint.

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1 98. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 99. Defendants state that this paragraph of the Complaint contains legal contentions to
7 which no response is deemed required. To the extent a response is deemed required,
8 Defendants admit that they had duties as are imposed by law but deny having breached such
9 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 100. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
16 Defendants state that Bextra® was and is safe and effective when used in accordance with its
17 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
18 were and are adequately described in its FDA-approved prescribing information, which was at
19 all times adequate and comported with applicable standards of care and law. Defendants deny
20 the remaining allegations in this paragraph of the Complaint.

21 101. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
23 deny the remaining allegations in this paragraph of the Complaint.

24 102. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

1 the Complaint.

2 103. Defendants state that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
4 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
5 paragraph of the Complaint.

6 104. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 105. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 Answering the unnumbered paragraph following Paragraph 105 of the Complaint, Defendants
11 deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the
12 remaining allegations in this paragraph of the Complaint.

13 **Response to Third Cause of Action: Breach of Express Warranty**

14 106. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 107. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
18 Defendants state that Bextra® was and is safe and effective when used in accordance with its
19 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
20 were and are adequately described in its FDA-approved prescribing information, which was at
21 all times adequate and comported with applicable standards of care and law. Defendants admit
22 that they provided FDA-approved prescribing information regarding Bextra®. Defendants
23 deny the remaining allegations in this paragraph of the Complaint.

24 108. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
26 Defendants state that Bextra® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
28 were and are adequately described in its FDA-approved prescribing information, which was at

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1 all times adequate and comported with applicable standards of care and law. Defendants admit
2 that they provided FDA-approved prescribing information regarding Bextra®. Defendants
3 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

4 109. Defendants deny the allegations in this paragraph of the Complaint.

5 110. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants admit that they provided FDA-approved prescribing information regarding
10 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 111. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants admit that they provided FDA-approved prescribing information regarding
16 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of
17 the Complaint.

18 112. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
20 Defendants admit that they provided FDA-approved prescribing information regarding
21 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 113. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 114. Defendants state that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
2 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
3 paragraph of the Complaint.

4 115. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 116. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 Answering the unnumbered paragraph following Paragraph 116 of the Complaint, Defendants
9 deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the
10 remaining allegations in this paragraph of the Complaint.

11 **Response to Fourth Cause of Action: Breach of Implied Warranty**

12 117. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
13 Complaint as if fully set forth herein.

14 118. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
15 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
16 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
17 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
18 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
19 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
20 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 119. Defendants admit that they provided FDA-approved prescribing information regarding
23 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that
24 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
25 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
26 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
27 prescribing information. Defendants deny the remaining allegations in this paragraph of the
28 Complaint.

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1 120. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
3 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
4 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
5 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
6 allegations in this paragraph of the Complaint.

7 121. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
9 Defendants state that Bextra® was and is safe and effective when used in accordance with its
10 FDA-approved prescribing information. Defendants deny the remaining allegations in this
11 paragraph of the Complaint.

12 122. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
14 Defendants state that Bextra® was expected to reach consumers without substantial change in
15 the condition from the time of sale. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 123. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
19 Defendants state that Bextra® was and is safe and effective when used in accordance with its
20 FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the
21 remaining allegations in this paragraph of the Complaint.

22 124. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 125. Defendants state that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
2 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
3 paragraph of the Complaint.

4 126. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 127. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 Answering the unnumbered paragraph following Paragraph 127 of the Complaint, Defendants
9 deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the
10 remaining allegations in this paragraph of the Complaint.

11 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

12 128. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
13 Complaint as if fully set forth herein.

14 129. Defendants state that this paragraph of the Complaint contains legal contentions to
15 which no response is deemed required. To the extent a response is deemed required,
16 Defendants admit that they had duties as are imposed by law but deny having breached such
17 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 130. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint, including all subparts.

28 131. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 132. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
11 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

12 133. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 134. Defendants deny any wrongful conduct and deny the remaining allegations in this
19 paragraph of the Complaint.

20 135. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 136. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 137. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 138. Defendants deny any wrongful conduct and deny the remaining allegations in this
5 paragraph of the Complaint.

6 139. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
8 Defendants state that Bextra® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
10 were and are adequately described in its FDA-approved prescribing information, which was at
11 all times adequate and comported with applicable standards of care and law. Defendants deny
12 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

13 140. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 141. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
21 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
22 paragraph of the Complaint.

23 142. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 143. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 Answering the unnumbered paragraph following Paragraph 143 of the Complaint, Defendants
28 deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the

1 remaining allegations in this paragraph of the Complaint.

2 **Response to Sixth Cause of Action: Unjust Enrichment**

3 144. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
4 Complaint as if fully set forth herein.

5 145. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
6 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
7 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
8 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
9 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
10 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
11 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
12 paragraph of the Complaint.

13 146. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 147. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 148. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
21 Defendants state that Bextra® was and is safe and effective when used in accordance with its
22 FDA-approved prescribing information. Defendants deny the remaining allegations in this
23 paragraph of the Complaint.

24 149. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

27 Answering the unnumbered paragraph following Paragraph 149 of the Complaint,
28 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,

and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief," Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

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Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff’s alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff’s alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff’s alleged injuries/damages, if any, were the result of preexisting or subsequent

1 conditions unrelated to Bextra®.

2 **Nineteenth Defense**

3 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the
4 doctrine of assumption of the risk bars or diminishes any recovery.

5 **Twentieth Defense**

6 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are
7 preempted in accordance with the Supremacy Clause of the United States Constitution and by
8 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

9 **Twenty-first Defense**

10 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
11 the subject pharmaceutical product at issue was subject to and received pre-market approval by
12 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

13 **Twenty-second Defense**

14 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
15 Plaintiff's Complaint was at all times in compliance with all federal regulations and statutes,
16 and Plaintiff's causes of action are preempted.

17 **Twenty-third Defense**

18 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
19 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
20 issue under applicable federal laws, regulations, and rules.

21 **Twenty-fourth Defense**

22 24. Plaintiff's claims are barred in whole or in part because there is no private right of
23 action concerning matters regulated by the Food and Drug Administration under applicable
24 federal laws, regulations, and rules.

25 **Twenty-fifth Defense**

26 25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate
27 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
28 of Comment j to Section 402A of the Restatement (Second) of Torts.

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Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of California and New Mexico, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of California and New Mexico. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in

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punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity

1 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

2 **Fifty-fifth Defense**

3 55. Defendants state on information and belief that the Complaint and each purported cause
4 of action contained therein is barred by the statutes of limitations contained in California Code
5 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation
6 as may apply.

7 **Fifty-sixth Defense**

8 56. Defendants state on information and belief that any injuries, losses, or damages suffered
9 by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable
10 conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against
11 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

12 **Fifty-seventh Defense**

13 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
14 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
15 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
16 damages is also barred under California Civil Code § 3294(b).

17 **Fifty-eighth Defense**

18 58. Plaintiff has failed to allege conduct warranting imposition of punitive damages under
19 New Mexico law.

20 **Fifty-ninth Defense**

21 59. The standards in New Mexico governing the award and review of damages for non-
22 pecuniary damages, including damages for mental anguish and pain and suffering, are
23 impermissibly vague or simply non-existent, and are inadequate to ensure that such awards do
24 not include amounts intended as exemplary damages, which are impermissible in a
25 compensatory damages award.

26 **Sixtieth Defense**

27 60. Plaintiff's claims for non-pecuniary damages are unconstitutionally vague and/or
28 overbroad, and are in contravention of Defendants' rights under various provisions of the New

1 Mexico Constitution, including but not limited to Art. II §§ 4, 13, 15, 18, and 19.

2 **Sixty-first Defense**

3 61. Defendants reserve the right to supplement their assertion of defenses as they continue
4 with their factual investigation of Plaintiff's claims.

5 **V.**

6 **PRAYER**

7 WHEREFORE, Defendants pray for judgment as follows:

- 8 1. That Plaintiff take nothing from Defendants by reason of the Complaint;
- 9 2. That the Complaint be dismissed;
- 10 3. That Defendants be awarded their costs for this lawsuit;
- 11 4. That the trier of fact determine what percentage of the combined fault or other liability
12 of all persons whose fault or other liability proximately caused Plaintiff's alleged
13 injuries, losses or damages is attributable to each person;
- 14 5. That any judgment for damages against Defendants in favor of Plaintiff be no greater
15 than an amount which equals their proportionate share, if any, of the total fault or other
16 liability which proximately caused Plaintiff's injuries and damages; and
- 17 6. That Defendants have such other and further relief as the Court deems appropriate.

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1 March 26, 2008

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11 March 26, 2008

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22 CORPORATION, AND G.D. SEARLE
23 LLC
24
25
26
27
28

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

March 26, 2008

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